

Award Number: W81XWH-08-1-0683

TITLE: Burn Patient Acuity Demographics, Scar Contractures, and Rehabilitation Treatment Time Related to Patient Outcomes (ACT)

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REPORT DATE: *October 2014*

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

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REPORT DOCUMENTATION PAGE		Form Approved OMB No. 0704-0188
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1. REPORT DATE (DD-MM-YYYY) October 2014	2. REPORT TYPE Annual	3. DATES COVERED (From - To) 18 Sep 2013 – 17 Sep 2014
4. TITLE AND SUBTITLE Burn Patient Acuity demographics, Scar Contractures, and Rehabilitation Treatment Time Related to Patient Outcomes (ACT)		5a. CONTRACT NUMBER W81XWH-08-1-0683
		5b. GRANT NUMBER
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S) Reginald Richard, email: reg.l.richard.ctr@mail.mil		5d. PROJECT NUMBER
		5e. TASK NUMBER
		5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) American Burn Association 311 S. Wacker Dr Suite 4150 Chicago, IL 60606		8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, MD 21702-5012		10. SPONSOR/MONITOR'S ACRONYM(S)
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited		
13. SUPPLEMENTARY NOTES		

14. ABSTRACT

The ACT study finished its sixth year of operation reaching two milestones. First, all subject enrollment and data collection was concluded. Final total number of subjects in the study was 307. Second, with the over sampling of larger burns during the past year, the results stayed the course. Data analyses showed that for all burn groups, small and large, that increased burn rehabilitation time provided during acute hospitalization resulted in less burn scar contracture. Due to high fiscal responsibility, a final no cost extension was requested to support further data analyses.

15. SUBJECT TERMS

Burns, Scars, Contractures, Rehabilitation, Outcomes

16. SECURITY CLASSIFICATION OF:**a. REPORT****U****b. ABSTRACT****U****c. THIS PAGE****U****17. LIMITATION
OF ABSTRACT****UU****18. NUMBER
OF PAGES****39****19a. NAME OF RESPONSIBLE PERSON
USAMRMC****19b. TELEPHONE NUMBER** *(include area code)*

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Introduction

Burn Patient Acuity Demographics, Scar Contractures, and Rehabilitation Treatment Time Related to Patient Outcomes, conveniently referred to as the ACT for representing Acuity, Contractures and Time in the title, is a burn rehabilitation research project awarded by the U. S. Army Medical Research and Materiel Command (MRMC) to the American Burn Association (ABA) in September 2008. As an overview, the ACT was conceived with the intention to accomplish two aims. The first aim of the ACT was to convene a consensus meeting of experienced rehabilitation providers to discuss the current state of affairs and future directions for burn rehabilitation care and research. This aim was successfully accomplished during the first year with protracted positive effects as detailed in the 2102 Annual report.

The ACT's second aim was to conduct a prospective, multi-center study on burn rehabilitation, the progress to date of which is elaborated upon in the remainder of this report. The purpose of the ACT is to investigate patient recovery from burn injury during the acute and intermediate phases of burn rehabilitation through the collection of daily treatment information for analysis. In particular, the ACT is primarily interested in investigating the influence that time spent receiving rehabilitation treatments has on patient outcomes as a reflection of patient acuity.

The sixth year of ACT operations ended in September 2014 by way of a second, two-year No Cost Extension (NCE) that became necessary to continue on with data collection. The first two years of the ACT were consumed with establishing the study structure. The bulk of the third and fourth years were dedicated to data collection and audit. The fifth year was allocated to continued data collection which was interrupted by an organizational request for an interim data analysis that demonstrated the ACT essentially had fulfilled the Statement of Work. However, due to availability of sufficient financial resources, the ACT, in its preceding sixth year, continued to collect data on an underrepresented group of larger burns. As of this report, all agreed upon data collection has ceased, data audits have been successfully performed, and statistical analyses have been undertaken and further reported herein. The ACT has begun study and site closure as well. Finally, a third and final request for an additional one-year No Cost Extension has been requested to allow use of remaining available funds to support further formal data analyses.

Body

Aim 1

A burn rehabilitation summit meeting was held in 2008 as a previously reported ACT first year accomplishment activity. A summary publication of the meeting¹ was produced as well as three subsequent publications as previously reported.²⁻⁴ (Appendix A).

Aim 2

Pathologic burn scar contractures that limit joint range of motion and function are problematic for the burn survivor. Although scar contractures become apparent following wound closure, the biologic process to repair and close the burn wound leading to scar contracture begins almost immediately after the burning process stops during a patient's acute hospitalization. Rehabilitation treatments delivered prior to beginning the long-term rehabilitation phase of care are paramount to successful patient outcomes. It is the interaction of the type of treatments provided, beginning at patient admission to the burn treatment facility up until patient discharge, coupled with rehabilitation treatment time which constitutes the important data collection features of the ACT.

During the past year, the follow-on data collection subsequent to the interim analysis was successfully completed and the ACT study officially closed to subject enrollments. Details and results of these processes are provided later in this report.

Organizational Structure

The structure of the ACT has remained constant during the past year in terms of organizational involvement of its three primary components: ABA, the U. S. Army Institute of Surgical Research (ISR) as the lead clinical site, and the University of California-Davis (UCD) as the central Data Coordinating Center (DCC) with regulatory responsibilities. During the last year, the ACT statistician changed his employment. However, he agreed to continue on a private basis to perform analysis of the ACT data.

Logistics

Interim Progress Report Meeting

In November 2013, an Interim Progress Report (IPR) meeting was held in San Antonio TX to discuss the status of the ACT (see Appendix B). A total of twenty-three (23) individuals attended, including the lead Principal Investigator, representing various aspects of the ACT study as well as representing various participating sites. Eight (8) of

the fourteen (14) ACT sites were represented by sixteen (16) individuals. Sites not officially represented were: Arizona Burn Center; University of California – Irvine; St. Joseph Burn Center; University of California – Davis; Oregon Burn Center and NY Presbyterian Hospital. Additional representatives included those from the ABA Central Office (2), Data Coordinating Center (2), ABA Burn Science Advisory Panel (2) and ACT statistician.

A primary purpose was to review the data and statistics that supported submission of two ABA abstracts for presentation at the 2014 ABA Meeting. The majority of time during the IPR was taken up discussing ACT data and contents of the ACT-ABA abstracts. Discussion was held about statistical approach to data analysis. Further debate was held on the status of the ACT relative to reporting conclusions based on the study enrollment in the abstracts.

Out of the IPR was formed and ACT Publication Committee. The purpose of the committee was to review requests for use of ACT data to encourage co-operation among participating facilities and avoid duplication of effort. Committee composition can be seen in Appendix C. Subsequently, a topic application was developed (Appendix D) and circulated to all participating ACT sites.

Data Collection

As a planned carry-on from the previous year, the five (5) participating sites who had offered to continue with contributing subject with burns greater than ten percent continued to do so (Appendix E). Patient screening with subject enrollment of the over-sample population ended on 31 December 2013. Subsequent submission of lingering data and audit of study records was continued until completed on 7 April 2014.

Investigators Meeting

As has occurred in previous years, an ACT Investigators meeting (IM) was held in conjunction with the annual meeting of the ABA in Boston MA. Twelve (12) individuals from 10 of 14 participating ACT sites were present including the PI. Additionally, two representatives from both the ABA and the DCC were present totaling 16 attendees.

The primary focus of the meeting was to relay and discuss the decision made by the Burn Science Advisory Panel (BSAP) of the ABA on how ACT data would be made available to participating sites, and then the ABA membership at-large. The decision by the BSAP/ABA was to give participating ACT sites one year to analyze what data they were interested in studying. Said year would include each site receiving the data from the DCC in time to prepare abstracts for the 2015 ABA meeting.

Following that time, in 2015, the data would be made available to the ABA membership at-large for use. Use of the data would be made by formal request of the ABA Central Office in a similar manner as to how access is given to data from the National Burn Repository of the ABA.

Data Access

To date, only the PI has received ACT data from the DCC. The updated data was delivered to the PI on 26 June 2014. Multiple inquiries by the PI were made as to when the other participating sites could expect to receive the data as well. The repeated answer was that the data was being re-formatted into a more useable form and because the ACT data set was so large that it was going to be a lengthy process. Additionally, there was protracted internal discussion among the PI, ABA, BSAP and DCC in terms of what would constitute the final data set. Further detail on this situation is available in the next sub-section. Unfortunately, the final ACT data set was not distributed to participating facilities so that they could have analyzed the data based on their respective interests.

Beyond the ACT data areas of interest assumed by the lead site (USAISR), topic requests by other sites (Appendix F) were unable to be undertaken because of the data disbursement delay. The USAISR, in conjunction with interested participating sites, was fortunate to generate two abstracts for consideration at the 2015 ABA annual meeting. Results of total study screenings and enrollments as well as data analyses for abstracts can be found elsewhere in this report. Determination outcome of these abstract will be made known in November 2014.

Data Audits

At the conclusion of the ACT study enrollments and subject record completion (7 April 2014), all subject data had been reviewed and audited by the study PI. Details on patient screening and subject enrollments along with sub-categorizations are reported on in the next section.

During the audits process, 35 records (10.2%) failed audit. The majority of these records were from two participating facilities. One of these two facilities failed to pass audit on any record by the time audit completion deadline. As a result, this was the principle reason that the data was not made ready for distribution as had been previously announced because of time spent in deliberations between the ABA, BSAP, DCC and PI in an attempt to find a resolution. At the time of this report, a solution to this situation remains ongoing.

Reportable Outcomes

Meritorious Recognitions

During the past year, the ACT study achieved two meritorious recognitions at the American Burn Association annual meeting. First, an ACT abstract reporting on the study's primary aim was selected as a Top 6 abstract for presentation at a newly established ABA Presidential Plenary Session.⁵ In total, 297 abstracts were accepted for presentation at this meeting. Second, another ACT abstract turned manuscript was selected to receive the 2014 ABA Burke/Yannas Bioengineering Best Paper Award.^{6,7} In addition, a third ACT data abstract was selected for presentation as well.⁸

Participant Screening and Enrollment

The ACT ended patient screening and subject enrollment at the close of December 2013. As per Appendix G, 4,621 patients in total had been screened at all 14 participating facilities. Appendix G also shows the accrual rate of subjects over time. As seen, a total of 307 subjects who successfully completed and passed data audit by the PI. This total equals 70.6% of the originally projected need of 435 subjects. Since last year (N = 284), 23 subjects were added to the study population during the over-sampling period.

For reporting purposes, the subjects (N = 307) in the consort diagram as seen in Appendix H will be used as it contains records from the thirteen (13) burn centers who contributed acceptable data. Although, 364 subjects had been enrolled into the ACT, 57 subjects were moved to an 'off study' status for the various reasons as shown. Twenty-four (24) subjects expired during the course of the ACT but none were attributable to the ACT study itself and thus did not trigger a reportable adverse event. Fifteen (15) subjects withdrew from the study voluntarily and another six (6) were deemed criteria failures. As an example of the latter situation, the patient was consented into the study but when the burn body diagram was completed, the patient failed to meet the minimum burn surface amount. It will be further noted, that in this grouping there remained an additional twelve (12) records that went unreconciled. All these records were from a second participating facility but because they had contributed some successful data to the study, their screenings and enrollments were maintained.

Subject Demographics

For the sanctity of the ACT study, subject demographics will be reported based on fourteen (14) participating sites to demonstrate that no prejudice or bias was involved in

in patient recruitment. Appendix I contains a comparison of subject demographics from the first annual report to the present.

Males comprised the majority of subjects which is consistent with national standards.⁹ Males initially were more accounted for most likely because to the U.S. Army Burn Center was the first to begin enrolling subjects. Ethnicity-wise, the number of Hispanic individuals remained almost the same during the three years of subject enrollments. From a race standpoint, the number of African American individuals likewise remained almost identical. Ultimately, the minor variability seen in subject subgroups was most likely attributable to the geographical locations of the participating burn centers. The consistency of these results continues to benefit from the supportive reason as listed in the 2013 report.

Subject Enrollment

Contributions to the data set by various participating burn centers is seen in Appendix J. Variance in percent contribution is due to two primary factors: 1) timing of IRB protocol approval and site training; and 2) facility capacity to enroll subjects at any given time. In terms of the latter reason, the ability of any given facility to enroll subjects was predicated on the availability of dedicated staff to support the ACT. Regardless, the ACT was able to summon a sufficient number of subjects to analyze data sufficient enough to support the Aim 2 of the project and to warrant study closure.

Appendix K is a breakdown of ACT subjects by percent decile burn that have been enrolled into the ACT inclusive of the over-sample period. As seen and anticipated, the 1 – 10 percent burn category contains the most number of subjects. The number of subjects expectedly decreases with increasing burn size. The aggregate total number of subjects with greater than 10 percent burn equals 130. The oversampling of the larger burns added 19 subjects to the study. For the purpose of the ACT study reporting to date, a comparison between the smaller burns ($\leq 10\%$) to the larger burns ($> 10\%$) will be made.

Key Research Accomplishments

The ACT's most resounding accomplishment during the last year was successful completion of subject enrollment and finalization of data collection and audit. From these data, two ABA abstracts were submitted for consideration for the 2015 annual meeting. The first abstract, titled "Small and Large Burns Alike Benefit from Lengthier Rehabilitation Time" is the mainstay of the ACT study. The bulk of the report in this section will be devoted to reporting on these results.

The second abstract, titled “Differential Assessment of Distal Interphalangeal Joint Flexion Limitation of Burn Fingers” was a secondary investigation. Part of the reason for this second abstract was to accentuate the depth of information available in the ACT data base. This abstract highlighted the missed assessment by clinicians to accurately evaluate limitation in motion of distal interphalangeal joint flexion. The results also emphasized the need to properly identify restrictive structures in order to properly plan patient treatment of the same.

Statistics

Variable used in the data analysis consisted of the 46 factors as seen in Appendix L. Descriptive statistics for continuous data is reported as medians with interquartile ranges (IQR) due to the data being skewed. Categorical data is reported as percentages. For continuous data, a T-test or Wilcoxon Two-Sample test was performed when appropriate. All categorical data was compared with a Chi-square test. All tests were two-sided using an $\alpha=0.05$. Logistic regression modeling including Receiver Operating Characteristics curve analysis was conducted to identify which factors were significant in developing a contracture and to evaluate logistic regression. After identifying those with and without a contracture, descriptive and simple statistical tests were performed to describe and compare the groups. Univariate analysis followed by Stepwise Forward and Multiple Logistic Regressions were performed to identify the most predictive variables of developing a burn scar contracture or limitation of motion which were the primary end points of the ACT. Reported results are based on use of data from thirteen participating burn centers as previously clarified.

Subject Acuity Demographics

Consistent with results reported last year and burns in general, the most common cause of burn injury remained flame or fire (Appendix M). Variables of interest or those found to be statistically significant for the total group (N = 307) are found in Appendix N. The information is also displayed for subgroups of Non-contracted (n = 64) and Contracted (n = 243) subjects. The median age for all groups was 42 years and the subjects were predominately male. Median hospital days were dependent on group category.

Inclusive of the over-sampling group, the total group was dichotomized into subjects with small burns i.e. $\leq 10\%$ Total body surface area (n = 177) and large burns i.e. $> 10\%$ Total body surface area (n = 130). Appendices O and P present the demographic breakdown of each group. The median age for each group was 43 and 41 years respectively and in both groups males predominated. For the $\leq 10\%$ group, the median

hospitalization was 12 days (approximately two days per percent burn) while subjects in the > 10% group were hospitalized approximately 18 days or one day per percent burn.

Primary Outcome Analysis

Of the total group of subjects (N = 307), 243 subjects (79%) had a burn scar contracture (BSC) or demonstrated a joint limitation of motion (LOM) at the time of discharge from their acute hospitalization. Sixty-four (64) subjects (21%) had neither identified BSC nor LOM. Overall, 8,068 joint ranges of motion (ROM) were measured and recorded. Of these joints, 5,285 joints (66%) had neither BSC nor LOM while 2,783 joints (34%) had an identified BSC or measured joint LOM. The number of scar contractures or limitations in motion is reportedly high compared to the literature. This high incidence may be a reflection that decreased ROM due to other sources than just burn scar contracture may be included and would benefit from further in-depth analysis.

Despite the over-sampling leading to increased representation of larger burns in the data set, the results follow a continuation pattern of last year's results. Subjects who developed a BSC or LOM were hospitalized longer, had a larger burn size and had more of their burn area skin grafted. However, subjects who averted BSC/LOM received significantly more rehabilitation treatment time attributed to either total body surface area or by cutaneous functional unit.

Interestingly, in both of the sub-groups, the only significant variable between subjects who did and did not develop a BSC/LOM was the amount of time per cutaneous functional unit received in favor of the latter. In both sub-groups, subjects without BSC/LOM received approximately twice as much or more time per cutaneous functional unit.

Regression Analysis

Multiple logistic regression analysis was performed for both sub-groups as well. Appendix Q lists the variables that met step-wise forward selection for inclusion after controlling for competing variables. In both cases, the common variables of age and gender were forced into the modeling process.

For both groups, the only significant variable identified by Odds-Ratio was the amount of rehabilitation time received by cutaneous functional unit (Appendices R & S). The interpretation of this information indicates for the $\leq 10\%$ group that for each additional minute of rehabilitation provided to each CFU the odds of developing a BSC/LOM decreases by seven percent. And, for the > 10% group, those odds decrease by 35%.

For both instances as part of the model, Receiver Operating Characteristic (ROC) Curves were generated and Area Under the Curve (AUC) calculated. In the cases of the $\leq 10\%$ burns, the AUC was calculated at 0.65 indicating a fair fit of the model. However, for the $> 10\%$ burns, the AUC generated was 0.83 indicating a good fit of the model.

Furthermore, when developing the model, an interaction effect was seen between the two groups. In this case, a statistically significant difference (p-value = 0.0014) was found between the two groups in favor of the larger burn group. In this circumstance, the interpretation is that, although both groups benefitted from lengthier burn rehabilitation time, the subjects in the larger burn group benefitted more.

Budget – See Appendix T

Conclusion

Within the last twelve months, the ACT attained two significant milestones. First was completion of subject enrollment and data collection. Second was a data analysis to support the primary end-point of the study. Compared to the interim analysis of last year, the new analysis further reinforced the original findings while adding additional support as to the benefit of increased rehabilitation time leading to better patient outcomes in terms of less burn scar contracture.

The ACT remains financially sound and the last successful NCE has been very helpful in completing further data mining, analyses and results reporting. Full expenditure of remaining funds is expected by the end of the current period of performance; 17 September 2015

Appendices

Appendix A

References

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7. Richard R, Jones J, Parshley P. Hierarchical decomposition of burn body diagram based on cutaneous functional units and its utility. Burke/Yannas Bioengineering Best Paper Award – ABA 2014. J Burn Care Res 2015;36:33-43.
8. Richard R, Dewey WS, Anyan WR, Kemp-Offenberg J, Miller K, et al. Cutaneous functional units relate better than total body surface area to burn patient outcomes. J Burn Care Res 2014;35:S77.
9. American Burn Association, National Burn Repository 2014 Version 8.0.

Appendix B

ACT IPR Agenda

Hyatt Regency River Walk Hotel – 123 Losoya Street
San Antonio TX

Wednesday, 6 November 2013

7:00 – 8:00	Breakfast	Rio Grande Center
8:00 – 8:15	Welcome & Introductions	Rio Grande West
8:15 – 8:30	Review of ACT from beginning	
8:30 – 8:50	ACT Screenings & Enrollments Demographics & NBR	
8:50 – 9:00	Update on current extended enrollments	
9:00 – 10:00	Review and Discussion of ABA Abstract <i>Increased Rehabilitation Treatment Time Improves Patient Outcome</i> Copy attached and available at IPR	
10:00 – 10:15	Coffee Break	
10:15 – 11:00	Review and Discussion of ABA Abstract <i>Cutaneous Function Units relate better than Total Body Surface Area to Burn Patient Outcomes</i> Copy attached and available at IPR	
11:00 – 11:30	ACT Interim Analysis Satisfaction of ACT Hypothesis and Aims	
11:30 – 12:00	Update from ABA Central Office; Burn Science Advisory Panel (BSAP); Data Coordinating Center (DCC) and Discussion	
12:00 – 1:00	Lunch	
1:00 – 1:30	Continuation of ACT Oversight Discussion and ACT Close-ut	
1:30 – 2:00	Review of ACT data set contents Copy attached and available at IPR	
2:00 – 2:30	Breakout session sub-group discussion - topic one Breakout session sub-group discussion - topic two	

2:30 – 3:15 Large group topic discussion summary

3:15 – 3:45 Breakout session sub-group discussion - topic three
Breakout session sub-group discussion - topic four

3:45 – 4:30 Large group discussion summary

4:30 – 5:00 Day one summary

5:00 Dinner on own

Thursday, 7 November 2013

7:00 – 8:00 Breakfast Rio Grande Center

8:00 – 8:30 Group topic discussion Rio Grande West

8:30 – 9:00 Breakout session sub-group discussion - topic five
Breakout session sub-group discussion - topic six

9:00 – 9:45 Large group topic discussion summary

9:45 – 10:15 Breakout session sub-group discussion - topic seven
Breakout session sub-group discussion - topic eight

10:15 – 10:30 Coffee Break

10:30 – 11:15 Large group discussion summary

11:15 – 12:00 Future Funding and Burn Rehabilitation Directions

12:00 – 1:00 Lunch

1:00 – 2:00 Summary of IPR and information going forward

Appendix C

ACT Publication Group

Reg Richard, PT – ACT PI, Institute of Surgical Research

Sandi Wewerka, MPH – Research administration, Regions Hospital

Steve Morris, MD – Medical, University of Utah

Melinda Shetler, OT – Rehabilitation, University of Iowa

Ingrid Parry, PT – Non-ACT representative, Shriners Hospital for Children Northern California

Appendix D

ACT Publication Topic Request Form

Requestors Name:

Date of Request:

Burn Center:

Anticipated Completion Date of Project:

Collaborators and Burn Centers:

Title of Proposed Investigation: (Provide a working title of Abstract/Manuscript)

Funding Support:

Submission Site: (e. g. ABA, JBCR, J Trauma, Burns)

Purpose or Rationale:

Description of investigation approach:

Send completed form to: Reg Richard, MS, PT @ reg.l.richard.ctr@mail.mil

Appendix E

Burn Centers Continuation with Subject Enrollment >10 % Burn

1. Via Christi Medical Center – Wichita KS
2. University of North Carolina – Chapel Hill NC
3. St Elizabeth Medical Center – Lincoln NE
4. University of Iowa – Iowa City IA
5. Loyola University Medical Center – Maywood IL

Appendix F

ACT Data Topic Request Table

Date	Requestor	Title/Topic	Facility
3/25/14	Stephen Morris Walter Anyan Iris Faraklas	Effects of donor site location and thickness on graft healing time, function and scar contracture development	University of Utah
3/25/14	Walter Anyan Iris Faraklas Stephen Morris	Improving burn injury outcomes: What can burn therapy do?	University of Utah
3/25/14	Iris Faraklas Walter Anyan Stephen Morris	The effects of anabolic steroids, anticoagulants and hypoglycemic medications on the burn patient: Is there a best practice as it relates to function?	University of Utah
8/11/14	Michelle Thompson David Voigt Paul Edwards	A retrospective review of patients with burn trauma to their hands and forearms	CHI Health St Elizabeth Burn Center

Appendix G

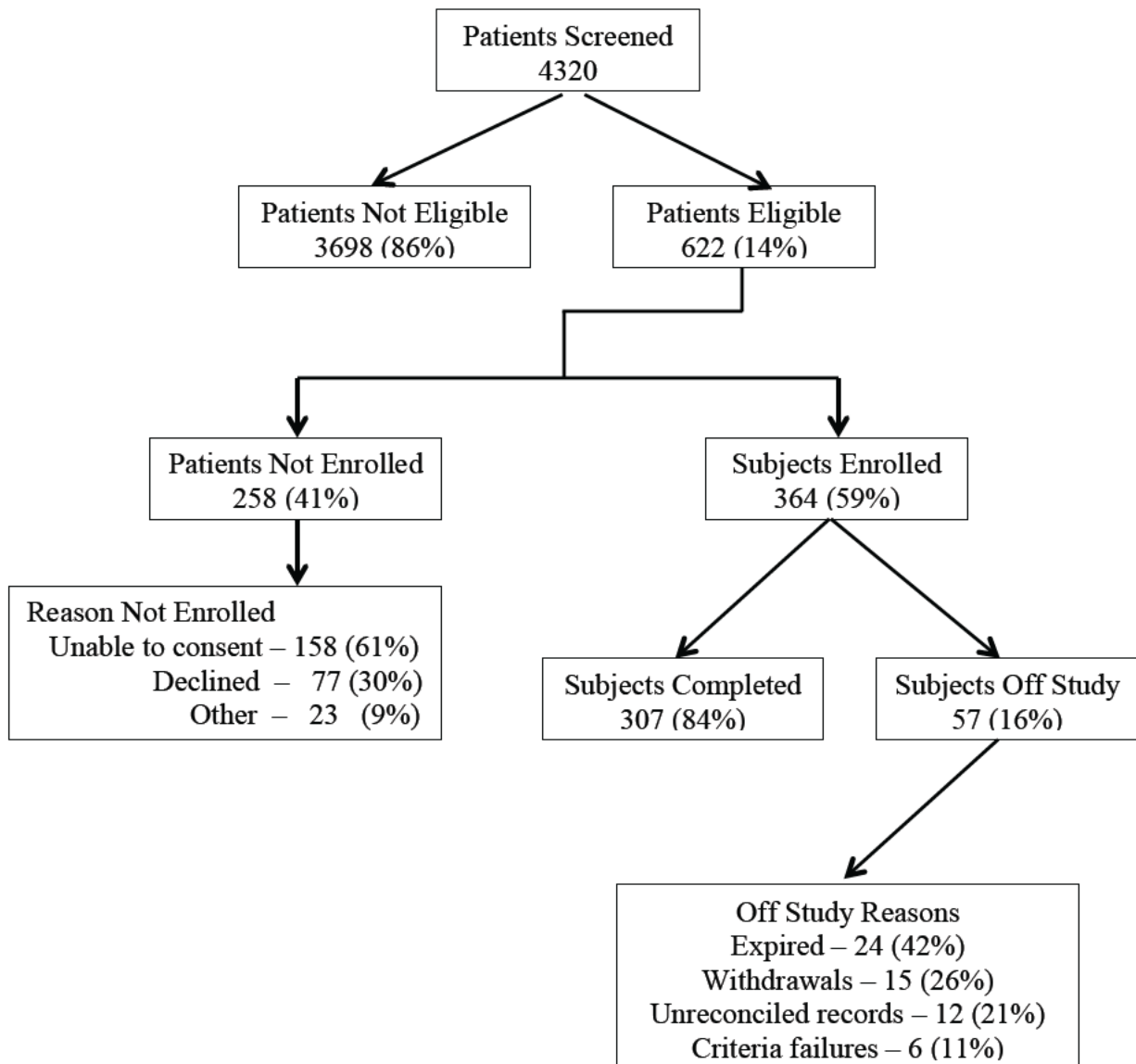
Patient Screening and Subject Enrollment*

	9/2011	9/2012	1/24/13	8/31/13	03/31/14	4/11/14 (Final)
# Sites Screening	7	11	11	5	0	0
Total Subjects Screened	745	3,163	4,141	4,371	4,621	4,621
Enrollment totals:						
Enrolled	43	239	318	328	336	307
*Off Study/Screen Failure	13	38	48	48	50	79
* Originally enrolled, later dropped. Data will not be included.						
Not Eligible	546	2,143	2,855	3,053		3,253
**Other	138	694	856	871		906
Declined	18	49	64	71		76

* Provided by Data Coordinating Center

Appendix H

ACT Consort Diagram



Appendix I

Comparison of Subject Demographic Information

<u>Year ending 2011</u>	Screened	%	Enrolled	%
Gender				
Male	569	76.4	43	76.8
Female	176	23.6	13	23.2
Ethnicity				
Hispanic	239	32.1	13	23.2
Non-Hispanic	472	63.3	38	67.9
Unknown	34	4.5	5	8.9
Race				
African American	72	9.7	6	10.7
American Indian/Alaska Native	1	<1	0	0
Asian	15	2.0	1	1.8
Caucasian	576	77.3	43	76.8
Native Hawaiian/Pacific Islander	1	<1	0	0
Not Reported	31	4.2	3	5.4
Unknown	49	6.6	3	5.4

Year ending 2014		Screened					Percentage of Final Known/Reported
		9/2011	9/2012	1/24/13	8/31/13	3/31/14	
Gender							
	Male	569	2,169	2,821	2,900	3,066	69%
	Female	176	994	1,266	1,312	1,399	31%
Not Reported/Unknown				54	159	156	
Ethnicity							
	Hispanic	239	683	823	832	847	24%
	Non-Hispanic	472	1,867	2,393	2,476	2,651	76%
Not Reported/Unknown		34	613	925	1,063	1,123	
Race							
	African American	72	270	332	338	360	11%
	Native American	1	15	19	19	19	<1%
	Asian	15	95	126	127	129	4%
	Caucasian	576	2,039	2,615	2,697	2,839	85%
	Pacific Islander	1	7	7	8	8	<1%
	Not Reported	31	259	311	311	318	
	Unknown	49	478	731	871	948	

Appendix J

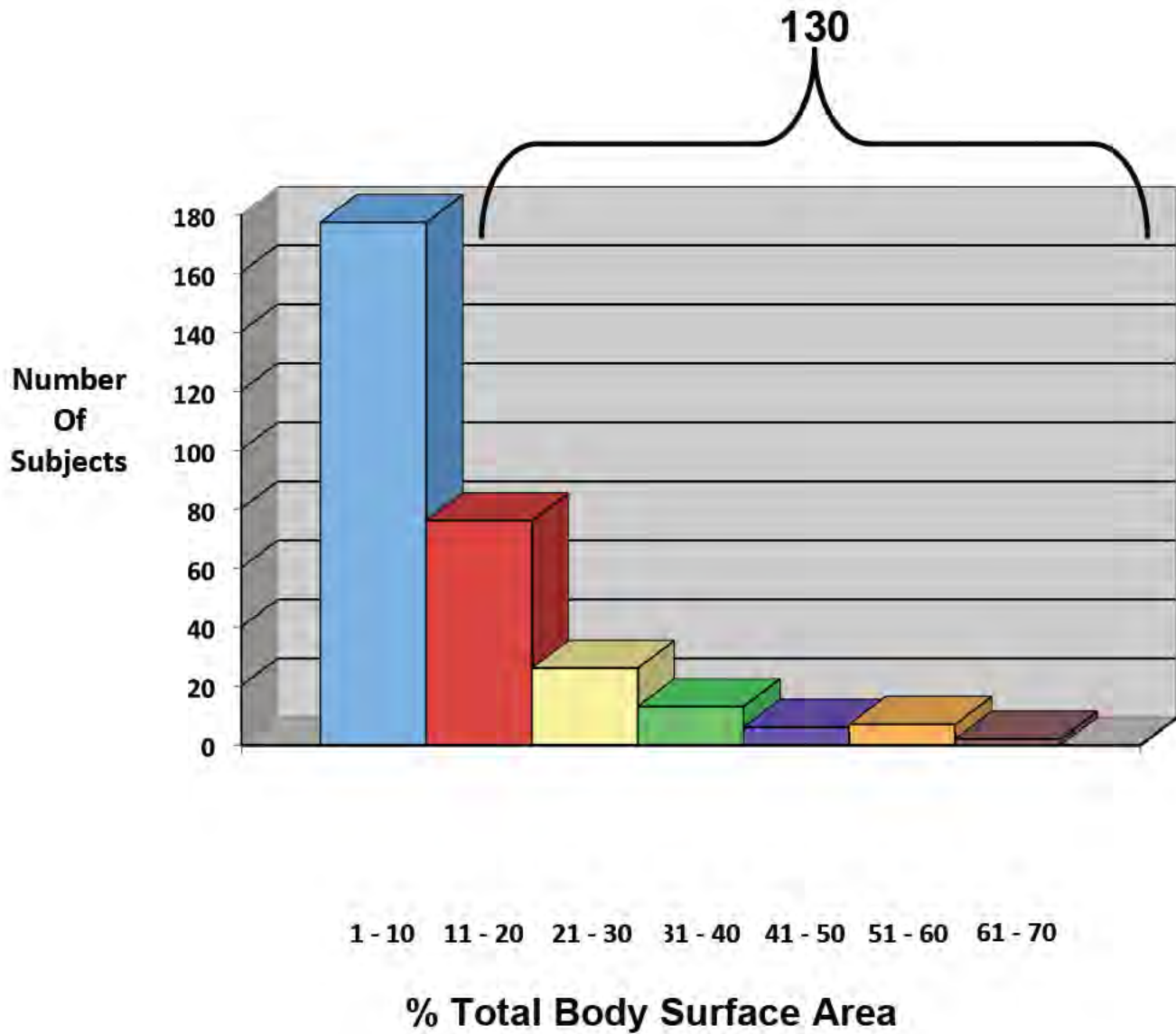
Site and Subject Enrollment

<u>Facility</u>	<u>Approved Subject Number</u>	<u>Enrolled[#]</u>	<u>Percent</u>
1. USAISR	75	72	96
2. Via Christi	35	11	31
3. Loyola Medical Center	75	18	24
4. St Elizabeth Medical Center	46	6	13
5. New York Presbyterian	60	15	25
6. Oregon Burn Center	60	3	5
7. St Joseph's Medical Center	50	5	10
8. University of Utah	75	75	100
9. Regions Hospital	26	21	81
10. University of North Carolina	25	15	60
11. Arizona Burn Center	125	35	28
12. University of California Irvine	50	18	36
13. <u>University of Iowa</u>	<u>75</u>	<u>13</u>	17
Total	852	307[#]	

Total number per DCC

Appendix K

Subject Enrollment per % Decile Burn Injury
(N = 307)



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Appendix L

Variables Used in Analyses

Age	Pre-existing medical condition
Gender	Concomitant injury
Height	Percent TBSA
Weight	Percent Superficial Partial-thickness
Hand dominance	Percent Deep Partial-thickness
Burn etiology	Percent skin grafted
Education level	Hospital length of stay (days)
Learning impairment	Inhalation injury – Yes/No
Psychological history	Ventilator use – Yes/No
ETOH/Drug use history	Ventilator days
Toxicology screen	Ventilator days/hospital days
Pre-existing physical problem	Escharotomy/Fasciotomy
Fracture – Yes/No	Total rehabilitation time (direct only)
Exposed tendon/bone	Daily rehabilitation time
Anabolic agent use	Daily rehab time/Total body burn
Thrombo-embolic event	Splinted – Yes/No
Rehabilitation days	Average splint time
Non-rehabilitation days	Rehabilitation compliance
Possible number of burn scar contractures	Pain tolerance
Total rehabilitation time	Amputation – Yes/No
Total non-rehabilitation time	Amputation location
Daily rehab time/Cutaneous Functional Unit	Heterotopic ossification
Rehabilitation days by hospitalization	Neuropathy

Appendix M

Burn Causes (N = 307)

Flame	71.3% (n =219)
Tar, Grease, Oil	11.4% (n = 35)
Hot Liquid	9.1% (n = 28)
Contact	5.2% (n = 16)
Friction	2.0% (n = 6)
Chemical	<1.0% (n = 2)
Hot Gas	<1.0% (n = 1)

Appendix N

ACT Subject Results*

Category	TG (N = 307)	NC (n = 64)	CG (n = 243)	p-Value#
Age (Years)	42 (29-55)	42 (28-54)	42 (30 – 56)	0.5474
Gender (% males)	71 (n=217)	69 (n = 44)	71 (n = 173)	0.7024
Hospital length of stay (days)	14 (10 - 22)	12 (8 – 17)	14 (10 – 24)	0.0201
% Total Body Surface Area	8.2 (4.4 – 15.7)	4.9 (3.4 – 8.6)	9.6 (4.6 – 17.9)	<0.0001
% Skin grafted	3.5 (0.7 – 7.7)	2.3 (0 – 4.6)	3.99 (1.1 – 8.6)	0.0010
Rehab time (Min)/Treatment	42 (29 – 59)	40 (24 – 52)	42.3 (29.7 – 61)	0.1034
Rehab time (Min)/TBSA	4.9 (2.7 – 8.3)	6.1 (4.1 – 10.1)	4.5 (2.4 – 7.9)	0.0031
Rehab time (Min)/CFU	2.2 (1.2 – 4.7)	4.4 (2.0 – 8.9)	1.8 (1.1 – 3.8)	<0.0001
*Data reported as Medians with inter-Quartile range (IQR) unless otherwise indicated; TG = Total Group; NC = Non-contracted Group; CG = Contracted Group; # NC vs. CG; TBSA = Total Body Surface Area; CFU = Cutaneous Functional Unit				

Appendix O

ACT Subject Results ≤ 10% Total Body Surface Burn

Category	TG (n = 177)	NC (n = 64)	CG (n = 243)	p-Value#
Age (Years)	43 (30.5 – 55.5)	43.5 (29.8 - 53)	43 (31 – 58)	0.7755
Gender (% males)	62 (n = 110)	64 (n = 32)	61 (n = 78)	0.7498
Hospital length of stay (days)	12 (8 - 15)	11 (8 – 16)	12 (8 – 15)	0.8281
% Total Body Surface Area	4.6 (3.3 – 7.0)	4.1 (3.0 – 6.2)	4.7 (3.5 – 7.2)	0.1217
% Skin grafted	2.2 (0.2 – 3.8)	2.1 (0 – 3.9)	2.2 (0.4 – 3.9)	0.5995
Rehab time (Min)/Treatment	37 (25 – 50)	33 (21 – 62)	37.5 (27 – 51)	0.2324
Rehab time (Min)/TBSA	7.2 (4.9 – 11.6)	7.1 (4.9 – 11.8)	7.4 (4.7 – 11.8)	0.9442
Rehab time (Min)/CFU	2.8 (1.6 – 5.9)	4.6 (1.9 – 9.5)	2.4 (1.4 – 9.8)	0.0020
*Data reported as Medians with inter-Quartile range (IQR) unless otherwise indicated; TG = Total Group; NC = Non-contracted Group; CG = Contracted Group; # NC vs. CG; TBSA = Total Body Surface Area; CFU = Cutaneous Functional Unit				

Appendix P

ACT Subject Results > 10% Total Body Surface Burn

Category	TG (n = 130)	NC (n = 14)	CG (n = 116)	p-Value#
Age (Years)	41 (28 – 44)	32.5 (23 – 56.5)	41 (29 – 55)	0.3575
Gender (% males)	82 (n = 107)	86 (n = 12)	83 (n = 95)	0.7238
Hospital length of stay (days)	18.5 (12.99 - 27)	18 (11– 29)	18.5 (13 – 37)	0.3068
% Total Body Surface Area	8.8 (4.3 – 15.6)	16.04 (12.4 – 22)	18.6 (13 – 29)	0.3502
% Skin grafted	2.2 (0.2 – 3.8)	8.8 (0 – 13.7)	8.8 (4.8 – 17.3)	0.2117
Rehab time (Min)/Treatment	51 (36 – 70)	56 (43 – 81)	49 (35 – 69)	0.3735
Rehab time (Min)/TBSA	2.7 (1.7 – 4.4)	3.5 (2.7 – 4.8)	2.5 (1.7 – 4.2)	0.0795
Rehab time (Min)/CFU	1.5 (0.96 – 2.9)	3.8 (2.5 – 6.2)	1.4 (0.9 – 2.6)	<0.0001
*Data reported as Medians with inter-Quartile range (IQR) unless otherwise indicated; TG = Total Group; NC = Non-contracted Group; CG = Contracted Group; # NC vs. CG; TBSA = Total Body Surface Area; CFU = Cutaneous Functional Unit				

Appendix Q

Variable Used in Logistic Regression Model

- 1) Age (Forced)
- 2) Gender (Forced)
- 3) Total body surface area burn[^]
- 4) Percent superficial partial-thickness burn[^]
- 5) Possible number of burn scar contractures/limitation in motion^{^, *}
- 6) Total direct rehabilitation treatment time[^]
- 7) Rehabilitation time per cutaneous functional unit^{^, *}
- 8) Rehabilitation time per total body surface area^{*}

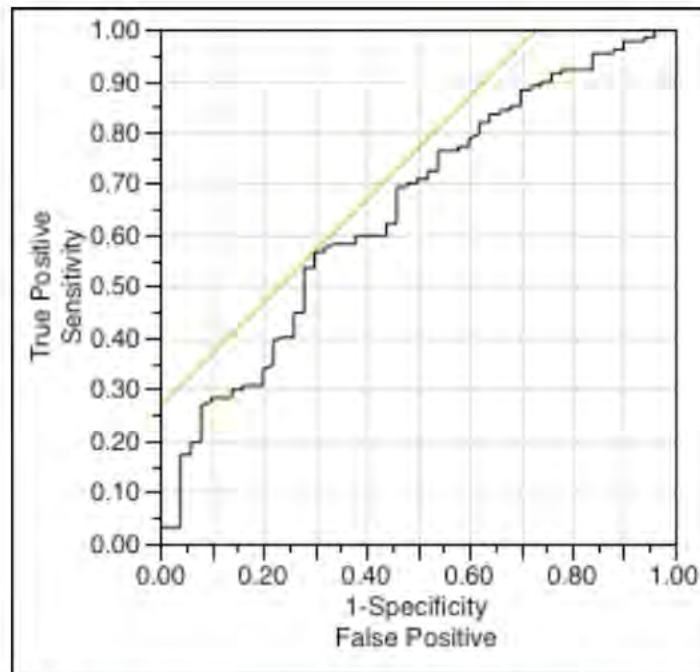
[^] \leq 10% burn

^{*} $>$ 10% burn

Appendix R

Regression Model

$\leq 10\%$ Burn (n = 177)		
Variable	Odds Ratio	95% CI
Rehab time/CFU	1.07	1.02 – 1.12

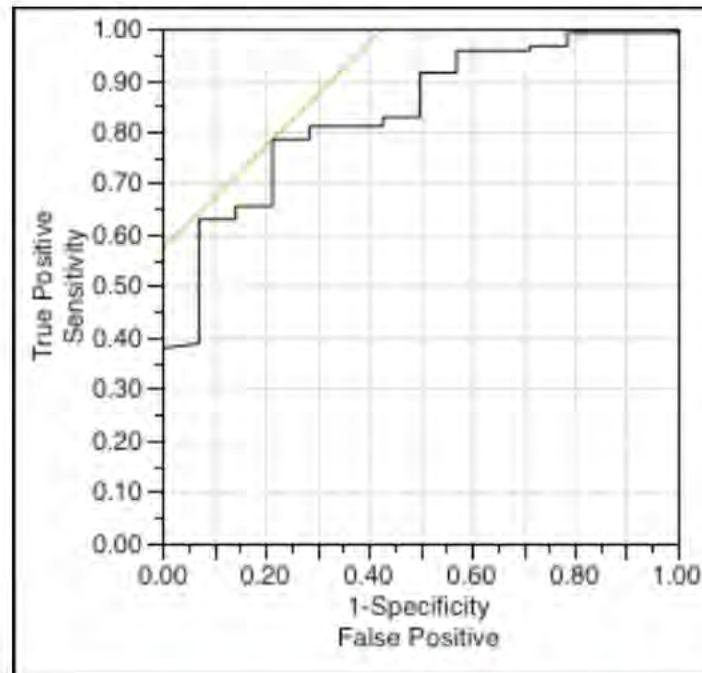


AUC = 0.64906

Appendix S

Regression Model

> 10% Burn (n = 130)		
Variable	Odds Ratio	95% CI
Rehab time/CFU	1.36	1.18 – 1.74



AUC = 0.83344

Appendix T - Budget Status

	BUDGET Total	CUMULATIVE EXPENDITURES thru 5/31/15	% of Total Budget Spent
PI	406,563	351,390	86.4%
Clinical Research			
Investigator	40,783	40,783	100.0%
Statistician/Biostatistician	157,923	108,823	68.9%
ABA Study Coordinator	76,271	61,077	80.1%
Legal/Accounting/Audit	76,832	75,867	98.7%
Travel ABA	10,089	13,455	133.4%
Domestic Travel	23,716	18,418	77.7%
Subsistence - Trainee	1,356	1,356	100.0%
Travel-Trainee Costs	12,400	12,400	100.0%
In Progress Review Meeting	31,737	31,737	
Materials and Supplies	67	67	99.3%
Consultant Services	59,535	59,535	100.0%
Per Patient Center Reimbursement	561,795	561,795	100.0%
Total ABA Direct Costs	1,459,067	1,336,703	91.6%
ABA Indirect Costs @ 15%	202,941	184,586	91.0%
ABA Total	1,662,008	1,521,289	91.5%
DROP	160,712	102,391	63.7%
Clinical Nurse Coordinator	152,502	80,803	53.0%
Database Programmer	45,037	97,515	216.5%
Regulatory Analyst	-	77,542	100.0%
DCC Total Direct Costs	358,251	358,251	100.0%
DCC Indirect Costs @ 22%	78,815	78,815	100.0%
DCC Total	437,066	437,066	100.0%
Grand Total	2,099,074	1,958,355	93.3%

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